DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 10, 2017

Visiomed AG
c/o Mr. John Greenbaum
Generic Devices Consulting
20310 SW 48th Street
Fort Lauderdale, Florida 33332

Re: K040171
Trade/Device Name: MicroDERM®
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: PSN
Dated: April 26, 2004
Received: April 27, 2004

Dear Mr. Greenbaum

This letter corrects our substantially equivalent letter of June 8, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040171

Device Name: MicroDERM

Indications for Use:

MicroDERM® is intended for the acquisition and storage of images of skin surfaces. These images can then be retrieved, printed, reviewed and displayed.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040171

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JUN - 8 2004

510(k) Summary

Submitter: Visiomed AG.
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Contact: Thomas Schnepple

510(k) Numbers and Product Codes of equivalent devices.

Apax Pacs System

510(k) Number: #K032760

Product Code: LLZ

CFR Section: 892.2050

Tis, Inc., Seoul Korea

Indications for Use and Intended Population

MicroDERM® is intended for the acquisition and storage of images of skin surfaces. These images can then be retrieved, printed, reviewed and displayed.

Device Description

MicroDERM® is a digital dermascope and software system, which captures images of skin surfaces for physician diagnostic review and referral purposes. These images can be sent to other computers using a modem or network card. It consists of the MicroDERM® camera, MicroDERM® software, and a frame grabber card. The MicroDERM® software runs under the Microsoft® Windows 2000 operating system. MicroDERM is not intended as a diagnostic device.

Physical/Technical Characteristics

MicroDERM® can digitize, display, store, retrieve and import images using the digital dermatoscopic, software and supporting PC hardware. Images are saved in a database using the standard JPEG image compression algorithms. Images can be exported to other devices (e.g. other MicroDERM systems) via a DICOM export function.

Performance Standards

The MicroDERM System has been tested to and meets the following Performance Standards:

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- ISO 9001:1994 – Quality Systems
- ISO 13485 – Quality Systems, Medical Devices- Particular application to the Requirements of 90001
- EN 14971 – Risk Analysis
- EN 46001 - Quality Systems - Application of 9001 to Medical devices
- IEC 10918-1 - Information technology -- Digital compression and coding of continuous-tone still images: Requirements and guidelines
- IEC 60601- Electrical Safety and Electromagnetic Compatibility
- 21CFR820 Quality System Regulation
- FDA ODE Guidance on the Content of Pre-market submissions for devices containing Software; 1998
- FDA Guidance of use of Off The Shelf Software in Medical Devices; 1997
- FDA Guidance for the Submission of Pre-Market Notification for Medical Image Management Devices; 2000
- 21CFR1020.10 – As applicable to Video Monitors
- 21CFR1040.10 – As applicable to Optical Storage Devices
- 21CFR810 - Labeling

Conclusion

There are more similarities than differences between the predicate device and the Visiomed AG MicroDERM System. When used in according with the directions for use, by qualified personnel, the Visiomed AG MicroDERM System is safe and effective, as indicated, for its intended use. No new issues of risk, safety or effectiveness are introduced with the Visiomed AG MicroDERM System when compared with the predicate device.